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Statistical Process Control Charts

To the Editor:

Statistical process control (SPC) is possibly the most enticing gadget in the industrial quality control toolbox. It promises much. While reading John Sellick's article,' an old aphorism came to mind: "There is no such thing as a free lunch."

The potentials of SPC are dual: A) that control charting of clinical variables will reveal "opportunities for improvement" by directing scrutiny to events that involve special causes of variation; and B) that a clinical process, once tuned to eliminate special cause variation, is as well-suited as it can be for alterations aimed at reducing common cause variation or producing more desirable mean values of a process variable. The *A-B* sequence is crucial to quality improvement (CQI). *A* feeds to CQI signals sorted from noise. *B* seems a safe approach to the hornet's nest inherent in improving clinical care because it limits opportunities for drawing erroneous cause-effect inferences after details of care are altered to improve outcome.

Shewhart[2] derived SPC from theoretical considerations that involve normal (ie, Gaussian) distributions, but it is a common misconception that SPC is hampered for processes whose inherent variation is other than normal. "Being in control" is not tantamount to "being in a normal (or Poisson or binomial) distribution" and vice versa. Dr. Sellick's discourse on SPC's origin hints that he may think otherwise. Wheeler and Chambers" have compared charting of normally distributed data and data from a variety of non-normal distributions (Burr, chi-square with two degrees of freedom, right triangle, uniform, and exponential) for hypothetical in-control processes. Shewhart 3-sigma charts give false alarms for a meager 1% to 2% of process data in this test. In these instances, SPC would have correctly advised managers with 98% to 99% accuracy to leave in-control processes unchanged.

I am confused by the statement that "the number of sigma that defines the control limits will determine the number of times that an out-of-control signal will be erroneous." This is nonsensical and should have been nailed by reviewers. What is meant by the word *erroneous?* A few pages later, the statement is made that "these charts should not be used for very infrequent events or small denominator samples." Is Sellick arguing that more data be gathered if infrequent defects are pursued? In what sense is "events" used here? Are "events" the denominator or the phenomena counted in numerators? The penalty of using small data sets in SPC is that genuine special variation may "hide" within putative common variation. However, this flaw cannot trigger ill-crafted CQI sorties. It is confusing to suggest that small data set control charts are "less accurate." They are just less useful, a different criticism.

SPC may hide useful CQI information. A case in point has emerged from our wound infection surveillance program." Using 1992 wound infection data in SPC (p-chart, 3-sigma limits), 86% of the complications appear as outcomes within common cause variation limits. SPC would suggest that the other 14% of flawed cases be searched for special causes of variation. Total case review in our system consistently reveals that about half of wound infections are associated with an identifiable departure from excellent practice. SPC would have led us to overlook a huge majority of cases, half of which on average contain valuable grist for the mill in feedback to surgical teams. This anecdote shows the conflicted linkage between putative variation causes and statistically defined special variation on a control chart. I think the conflict will haunt SPC applications to other prob lems in clinical care monitoring.

Many surgical outcome flaws lie in or below the same frequency range as wound infection and share its features of multifactorial etiology and few fully determinant preventative maneuvers. These thiigs make me worry that uncritical SPC use will hinder process improvement in my specialty (using Donabedian's definitions of "process" to denote technical aspects of care). Healthcare quality managers may shoot themselves in the foot by relying on SPC as a source for CQI projects, unwittingly confirming another old aphorism, "Out of sight, out of mind."

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The author replies.

Dr. Lee has reaffirmed the utility and potential shortcomings of statistical process control (SPC) charts. The risk of overreliance and overinterpretation were discussed in the "Caveats" section of the paper. Specific points raised by Dr. Lee bear comment:

1) Clearly, my intent in discussing attributes of SPC charts was to show that SPC theory can be used in the evaluation of nonparametric variables. However, the mechanics of generating the charts is based on normal approximations. Being "in (statistical) control" is defined by the fall of points within the control limits, which are based on the statistical distribution of data.'

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2) The number of σ that define the control limits determines the frequency of type I and type II errors.[2] "Erroneous" refers to these errors.

3) "Events" refers to the parts of the process being measured (such as surgical site infections) and tallied in the numerator. The caveat involved applies both to small numerators and denominators, since the *normal approximation* is less accurate with small numbers. This limits applicability of the described SPC charts in such circumstances.

4) I agree that potentially useful information may be hidden within SPC charts that are "in control." (I have greatest concern for small clusters of events that do not push points beyond control limits.) The example given by Dr. Lee highlights an important aspect of SPC chart theory, the determination of what is "acceptable" versus what is "in control." The "departure(s) from excellent practice" may be either common cause or special cause variations, and SPC charts can help assess the correction of either.

As I noted in the article, SPC charts should not be means or ends unto themselves. With proper interpretation and insight, they clearly provide a better means of monitoring processes than "bean counting."

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Iatrogenic Hepatitis B Infection of Three Patients in One Family

To the Editor:

In early winter 1992, a family (father, age 42 years; mother, 33 years; son, 9 years) visited a general practitioner in abu-Garib, a suburb of Baghdad, for management of respiratory tract infections. The physician prescribed some medications and gave each an injection, using a single syringe that, according to the patients, already had been used previously (a not uncommon practice in the rural areas). The family presented to me on June 18, 1993, with icterus and gastrointestinal complaints. Symptoms were mild for the father and mother, but the child had anorexia, a fever of 38°C, an enlarged, tender liver, and icterus.[1] Urine bilirubin was positive for all three, strongly so for the child. They provided serum for hepatitis B virus (HBV) testing, but refused further laboratory evaluation or inpatient treatment and were lost to follow-up. Assay for hepatitis B surface antigen (ELISA test, Abbot Laboratories, Chicago, IL) was positive for all three, as was the confirmatory test.

This small outbreak of hepatitis B most probably was caused by their physician's reuse of an unsterilized syringe and needle for intramuscular injection.[2] Every physician, especially in the developing countries, must keep in mind that some 350 million people are chronically infected with HBV; these carriers are the reservoir for HBV, and their blood is infectious.* With the improvement of screening and detection methods and their widespread use, iatrogenic infection with blood products has become rare in the developed countries.[3] In less developed countries, good infection control practices remain the principal line of defense.

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Blunt-Tipped Suture Needles

To the Editor:

We now have the opportunity to eliminate approximately two thirds of the sharps injuries that occur in our operating rooms and delivery rooms, through the use of blunt-tipped suture needles. I now use these for essentially all obstetrical and gynecological surgery. Most of the remaining one third of injuries can be prevented by passing sharps through a "neutral zone." Surgeons, nurses, and technicians can be protected from bloodborne pathogens, while hospitals can be saved the high cost of processing and dealing with these potentially devastating accidents and their sequelae.

The new blunt needles, like other product lines for O.R. safety, still are in their infancy: the manufacturers are striving to develop and refine them to suit the needs of more and more surgeons in various subspecialties. Meanwhile, the Centers for Disease Control and Prevention expresses great concern about poor compliance with safety practices by surgeons. This is in part due to surgeons' resistance to change; this must be overcome by education. The other major cause for noncompliance is surgeons' limited access to safety devices. Too many surgeons don't use eye protection or impervious gowns routinely, nor double glove routinely, because of their perception of these practices as nonuser-friendly; but those surgeons may not have seen yet the particular devices that could work for them in a user-friendly manner. No one would deny a carpenter a given tool if the desired result is a job well done. No less consideration should be given the surgeon, whose work is held to the highest standard. Too often, hospital cost-containment committees preselect and limit the menu of O.R. products. Surgeons are creative problem-solvers with individual needs. They alone should establish the selection criteria and must be allowed to choose those devices they feel will protect them best-devices that won't interfere with their ability to care for patients effectively. Even if extra pennies are spent to allow this to happen, the savings will

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